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REMARKS

Claims 1 – 14 are pending in the application. By this amendment, Claims 1-7 have been amended. New claim 15 has been added. Support for the amendments to Claims 1-7 and for new claim 15 can be found in the specification as originally filed, at least on pages 3, 4 and 5.

Election/Restriction

Applicant acknowledges the withdrawal of the election of species requirement on claims 1-7.

Claim Rejections – 35 U.S.C. § 112

Claims 1-7 were rejected under 35 U.S.C. §112, first paragraph. The Examiner stated that it does not appear that the specification supports general feeding steps which do not follow the sequence of low then high fat content and which do not even recite that the two compositions are given to the infant at the same feeding. The Examiner also stated that there appears to be an inconsistency in the specification which appears to define “fore-milk equivalent” and “hind-milk equivalent” as milk substitute which are “similar” or compatible” at least in their fat content “and/or” other ingredients. However, since it appears that the major defining difference between fore and hind milk is their fat equivalent, the Examiner questioned whether the applicant is disclosing that the two milk substitutes can have the same fat content and if so, could they then be truly termed fore and hind-milk?

In response, claim 1 has been amended to include a sequence of feeding steps, wherein the two feedings are performed sequentially during the same feeding. Applicants point out that support for general sequence steps can be found at least on page 3, line 5 of the specification as originally filed.

Furthermore, with regard to the Examiner’s assertion of an inconsistency, Applicant respectfully asserts that the statement in the specification referred to by the Examiner merely compares fat content of fore-milk equivalent to human fore-milk and of hind-milk equivalent to human hind-milk, and does not attempt to compare the fat contents of the two milk equivalents with each other. This should be clear from the statement itself which states: “The terms ‘fore-milk equivalent’ and ‘hind-milk equivalent’ therefore refer to milk substitutes, as this term defined herein, which are similar or compatible at least in their fat content and/or other ingredients to human

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fore and hind milk, respectively." (see specification as originally filed, page 4, line 35 to page 5, line 2, emphasis added). Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, first paragraph rejection.

Claim Rejections – 35 U.S.C. § 102

Claims 1, 2, 3 and 6 were rejected under 35 U.S.C. § 102(b) as being anticipated by Woolridge et al. (Lancet, vol. ii, 8207, p. 1292-1294, 1980). The Examiner stated that Woolridge et al discloses feeding an infant low fat milk and then high fat milk "simulating the change in milk composition during breast feeding." According to the Examiner, Woolridge anticipates Claim 1 since Woolridge et al meets the definition of a foremilk and hind-milk equivalent (i.e., one that is similar or compatible at least in their fat content), and that the milk is also a substitute since, at the minimum, it has been modified. Furthermore, the Examiner stated that in regard to Claim 3, Woolridge et al. disclose that the two milk portions are fed to the child one after the other, that in regard to Claim 6, Woolridge et al. disclose using two bottles, and in regard to Claim 2, since the objective of Woolridge et al. is to produce a milk simulating the change in milk composition during breastfeeding, Woolridge et al. would anticipate the recognized fat content for fore-milk that is recited.

In response, Applicant respectfully asserts that at least according to the abstract provided by the Examiner, Woolridge et al. are referring to altered breast milk and not to infant formula, as claimed in the present application. This is clearly stated in the first sentence, "Breast milk was centrifuged and the fat was added to other milk to give high and low-fat breast milk" (emphasis added) and is further evidenced by the title "Does a change in the composition of human milk affect sucking patterns and milk intake?" (emphasis added). Thus, at least based on the abstract, there is no evidence that Woolridge et al. disclose a fore-milk equivalent formula or a hind-milk equivalent formula, as claimed in amended Claim 1 of the present application.

Furthermore, with respect to Claim 3, Woolridge et al. clearly does not disclose first feeding said fore-milk equivalent which is gradually admixed with said hind-milk equivalent, as claimed in Claim 3 of the present application.

Thus, Applicant respectfully asserts that Claim 1 is not anticipated by Woolridge et al. and that Claims 2, 3, and 6, which depend therefrom are also not

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anticipated by Woolridge et al. Thus, Applicant respectfully requests withdrawal of the 35 U.S.C. § 102 rejection.

Claim Rejections - 35 U.S.C. § 103

Claims 2, 4 and 5 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Woolridge et al. in view of Stehlin (FDA consumer V. 30, 6/96, p. 17-20), Kavanagh (Food Ingredients. Europe, 11/95, 123-126), Uhle (Mil Chwissen Schaft, 29 (5), 265-274, 1974) and Zubkova et al (xix Int'l Dairy Congress, Vol. 1E, p639, 1974). The Examiner stated that claims 4 and 5 differ from Woolridge et al. in their percentage of foremilk and that to modify Woolridge et al. and vary the percentages of fore to hind milk is seen to have been an obvious routine determination. Furthermore, the Examiner stated that Stehlin, Kavanagh, Uhle and Zubkova are replete with teachings to simulate, copy, reproduce or imitate, human breast milk.

In response, Applicant respectfully traverses the Examiner's rejection, and asserts that as argued above with respect to the rejection of independent Claim 1, Woolridge et al. is referring to altered breast milk and not to formula, as claimed in the present application. Accordingly, at least for the reasons discussed in regard to Claim 1 above, Applicant respectfully asserts that Claims 2, 4 and 5 which directly or indirectly depend therefrom are allowable.

Claim 7 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Woolridge et al. in view of Simmons et al. (USSN 5,611,776). The Examiner stated that Claim 7 differs from Woolridge et al. in how the two milk compositions are delivered to the child and that it is well established to feed a child two different liquids by employing a two-compartmented bottle. The Examiner stated that it would have been obvious to modify Woolridge et al. and substitute one conventional delivery system for another conventional delivery system.

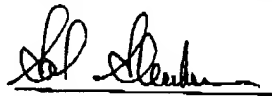
In response, Applicant respectfully traverses the Examiner's rejection, and asserts that as argued above with respect to the rejection of independent Claim 1, Woolridge et al. is referring to altered breast milk and not to formula, as claimed in the present application. Furthermore, a combination of Simmons et al and Woolridge et al. would not result in a design in which the infant is able to consume at first said fore-milk equivalent and thereafter said fore-milk equivalent gradually admixed with

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said hind-milk equivalent, as claimed in Claim 7 of the present application. Accordingly, at least for the reasons discussed, Applicant respectfully asserts that Claim 7, which directly depends from Claim 1, is allowable.

In view of the foregoing, it is submitted that all the claims now pending in the application are allowable over the cited reference. An early Notice of Allowance is therefore respectfully requested.

Respectfully submitted,



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